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Clinical Trial Synopsis

EudraCT number	2008-003555-77
Trial identification	
Full title of the study	Evaluation of the interest of combining a homeopathic treatment to conventional antiemetic management in the prevention of delayed nausea during the first two chemotherapy cycles, in thoracic cancers. (*Evaluation de l'intérêt d'associer un traitement homéopathique à la prise en charge antiémétique conventionnelle dans la prévention des nausées retardées lors des deux premières cures de chimiothérapie dans les cancers thoraciques*)
Abbreviated title	HONAURE
Sponsor protocol code	N° IB-2008-01
Investigational medicinal products (IMP identification)	Homeopathic medicinal products: Ignatia Amara 7 CH Phosphorus 9 CH
Sponsors	
Sponsor	BOIRON Laboratories
Sponsor Address	2 Avenue de l'Ouest Lyonnais 69510 Messimy FRANCE
Study Contact	Isabelle CHANEL, Research & Development & Scientific & Medical Affairs Director BOIRON Laboratories isabelle.chanel@boiron.fr
Scientific Contact	Dr Pierre-Jean SOUQUET 69310-FR
Research Location and Sites	FR – 2 investigative sites
Member State Concerned	AFSSAPS (ANSM) - France
Results Information	
Actual start date of recruitment	07 JAN 2009
Global end of trial date	(*date of the end of participation of the last person included in the research*) 03 MAR 2010
Planned number of subjects to be included- Country	44 (France)
Number of subjects enrolled - Country	36 (France)
Clinical Trial Phase	III

Clinical Trial duration	14 months
Publication reference	none
General information about the trial	
Clinical Trial Type:	Therapeutic confirmatory
Design of the trial	Pilot - Controlled – Randomized - Double blind - Parallel group – Comparator (Placebo)
Medical Condition	Hemodialysis-induced muscle cramps
Main objective of the trial	The main objective of this study was to evaluate the efficacy of a homeopathic treatment, combining Ignatia Amara 7CH and Phosphorus 9CH *versus* placebo, in addition to the conventional anti-emetic protocol for the prevention of chemo-induced delayed nausea, during the first cycles of chemotherapy with cisplatin (high emetogenic risk) in patients with thoracic cancer and treated for the first time.
Secondary's Objectives of the trial	The secondary objectives were: - To evaluate the efficacy of a homeopathic treatment, combining Ignatia Amara 7CH and Phosphorus 9CH, in addition to the conventional anti-emetic protocol for the prevention of chemo-induced delayed nausea, during the second cycle of chemotherapy, versus placebo. - To assess the efficacy of Ignatia Amara 7CH and Phosphorus 9CH in the overall management (nausea and vomiting) of acute and delayed emetic manifestations induced by cisplatin-based chemotherapy. - Evaluate the impact on patients' quality of life through the questionnaire "FLIE", - To assess the impact on anorexia and weight loss, - -To assess the impact on creatinine clearance, - -To assess adherence to homeopathic treatment, and allopathic anti-emetic treatment, - To assess the clinical tolerance of homeopathic treatment.
Principal Inclusion Criteria	- Male or female of at least 18 years of age who had undergone a clinical examination appropriate for research - Patient with confirmed thoracic cancer requiring chemotherapy treatment - Patient who had never been treated with cancer chemotherapy previously - Patient eligible and scheduled to receive his 1st cycle of chemotherapy containing mandatorily cisplatin (administered on Day 1) among the following 5 protocols: Protocol 1: Cisplatin 80 mg/m² (IV infusion) on Day 1 - Gemcitabine 1250 mg/m² (infusion) on Days 1 and 8 Protocol 2: Cisplatin 80 mg /m² (IV infusion) on Day 1 - Vinorelbine 30 mg / m² (IV infusion) on Day 1 and Day 8

	Protocol 3: Cisplatin 80 mg /m² (IV infusion) on Day 1 - Vinorelbine 25 mg / m² (IV infusion) on Day 1 and Day 8, before concomitant radiotherapy during the 3rd cycle of chemotherapy Protocol 4: Cisplatin 100 mg/m² (IV infusion) on Day 1 – Etoposide 100 mg/m² (IV infusion) on Day 1 to Day 3 Protocol 5: Cisplatin 75 mg/m² (IV infusion) on Day 1 – Pemetrexed 500 mg/m² (IV infusion) on Day 1 - Patient scheduled to receive conventional allopathic anti-emetic therapy for each chemotherapy cycle - Patient with an ECOG index < 3 See **Section E.3** for others
Principal Exclusion Criteria	- Patient who is pregnant, breastfeeding or of childbearing potential and not using reliable contraception - Patient who experienced nausea and/or vomiting within 5 days prior to enrolment - Patient who has used in the 24 hours preceding the induction of chemotherapy any drug with a potential anti-emetic action or using anti-emetics chronically - Patient scheduled for external cerebral and/or abdominal radiotherapy See **Section E.3** for others
Trial Status:	Completed
Statistical Analysis Description	No interim analysis was foreseen by this protocol. Qualitative data were described by their frequency and percentage. Missing data were not included in the calculation of percentages. The comparison of qualitative variables between groups T (Placebo) and H (Homeopathic treatments) was performed using a Chi^2 test or an exact Fisher test, if conditions for the application of Chi^2 were not met. Quantitative data were described by the number of data, mean, standard deviation, median, minimum, and maximum, and number of missing data if necessary. The comparison of quantitative variables was carried out with a t-Student, or by a nonparametric Wilcoxon test if the conditions of the parametric test were not met. If treatment groups had stark differences at baseline, Covariance analysis models could be implemented. Subgroup analyses were carried out considering the effectiveness of anti-emetic treatment in the acute phase. Two subgroups were therefore identified: the "high risk" group (for patients experiencing acute nausea and vomiting) and the "low risk" group (for patients who do not experience nausea or vomiting in the acute phase). A difference was found to be significant for a value of $p<0.05$ (risk of 1st species granted $\alpha=5\%$) in bilateral situation for all statistics tests during analysis. The effectiveness analysis was able to focus on two phases related to chemotherapy:

	- acute period (0-24 hours post-chemotherapy or Day 1 and Day 21). - delayed period (24-120 hours post-chemotherapy or from Day 2 to Day 6 and from Day 22 to Day 26)

Summary – research Findings

This pilot study conducted in patients with thoracic cancer treated for the first time did not show effect on delayed chemo-induced nausea of combining homeopathic treatment (Ignatia Amara 7CH and Phosphorus 9CH) with a conventional anti-emetic protocol.
However, the results of this study suggested a beneficial effect of the homeopathic treatment on the time to onset of nausea. Patients tolerated well their homeopathic treatment. Finally, although the statistics tests were not significant, this study showed a trend beneficial of homeopathic treatment on the intensity of nausea.

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Name & Function Signature : Date of Transmission	Isabelle Chanel Director of Research & Development & Scientific & Medical Affairs. 15 MAR 2023